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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	Phillip et al.
Serial No.	:	09/719,726
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For	:	Z AXIS TRACKER

CLAIM FOR PRIORITY UNDER 35 U.S.C. § 119

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Signature — Date of Signature

Assistant Commissioner for Patents

Washington, D.C. 20231

Sir:

A claim for priority is hereby made under the provisions of 35 U.S.C. § 119 for the above-identified PCT application based upon Australian application No. PP 4202 filed June 17, 1998, and International Application PCT/AU99/00479 filed June 17, 1999.

Respectfully submitted,

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I, KIM MARSHALL, MANAGER PATENT OPERATIONS, hereby certify that the annexed is a true copy of the Provisional specification in connection with Application No. PP 4202 for a patent by THE LIONS EYE INSTITUTE OF WESTERN AUSTRALIA INCORPORATED filed on 17 June 1998.

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WITNESS my hand this Fourteenth
day of July 1999

KIM MARSHALL
MANAGER PATENT OPERATIONS

PRIORITY DOCUMENT

SUBMITTED OR TRANSMITTED IN COMPLIANCE WITH RULE 17.1(a) OR (b)

AUSTRALIA

Patents Act 1990

PROVISIONAL SPECIFICATION

Applicant(s):

THE LIONS EYE INSTITUTE OF WESTERN AUSTRALIA INCORPORATED

Invention Title:

Z AXIS TRACKER

The invention is described in the following statement:

Z AXIS TRACKER

The present invention relates to a method and apparatus for tracking the position of a surface to accurately place a laser's focal point during surgical laser procedures, of application - for example - in operations involving intrastromal ablation of the cornea, in the refractive correction of the eye, and in phacoemulsifaction procedures, where the lens of the eye is liquefied for easy removal. The invention will be described in terms of these applications, but is not restricted thereto. For example, it will be understood that the present invention may be applied to other medical laser procedures in which depth monitoring is required.

Intrastromal Photorefractive Keratectomy (intrastromal PRK or IPRK), also known as intrastromal ablation, involves focusing a short pulsed (< 50 ns), near infrared or visible laser to a point inside the cornea. Unlike the excimer laser, short-pulsed visible and near infra-red lasers are not absorbed highly enough by biological tissue to cause photodissociation or "ablation". Instead, the mechanism of tissue removal involves plasma-mediated photodisruption, with the development of cavitation bubbles and shock waves beneath the laser's target zone. If a sufficient energy density is reached inside the tissue, optical breakdown occurs and a small volume of tissue at the laser's focal point is vapourised.

A number of studies have been conducted into the feasibility of using intrastromal PRK for correcting refractive errors of the eye (see for example Habib, Speaker, Kaiser & Juhasz (1995), or Ito, Quantock, Malhan, Schanzlin & Krueger (1996)). Intrastromal PRK leaves the corneal epithelium and endothelium intact, preventing potential complications such as infection, and facilitating wound healing. Tissue effects appear confined to the

cornea's stromal area, with small thermal damage zones and the appearance of normal collageneous stroma by six months post-surgery, with the use of the ultrashort Nd:YLF laser in cat cornea (Habib, Speaker, Kaiser & Juhasz (1995)). Intrastromal PRK may therefore have the ability to provide a more predictable refractive outcome, with the prospect of fewer complications than may occur with conventional techniques. US Patent 5,112,328 describes a method and apparatus for applications involving intrastromal corneal ablation.

It has been suggested that the intrastromal technique can be used to remove an appropriate volume of tissue, to effect refractive corrections in a similar fashion to those achieved in Laser-in-situ-Keratomileusis (LASIK) procedures, without the necessity of creating a flap, or to cut the flap during LASIK operations. The current microkeratomes used in refractive surgery such as LASIK are mechanical devices that have significant potential to malfunction, sometimes causing serious damage to a patient's eye. Using intrastromal ablation to create the flap in LASIK may be much easier than trying to use intrastromal ablation to effect a refractive change. The intrastromal flap has the potential to make LASIK a safer and simpler procedure to perform, without having to rely on the use of mechanical devices.

Although there may be significant advantages in using intrastromal ablation for procedures such as refractive laser surgery, the practical difficulties of aiming each laser pulse onto the correct location within the cornea has meant that IPRK is not yet routinely performed. In living eyes, the need to deposit each laser pulse in the correct spot places stringent requirements on tracking the eye not only in the horizontal and vertical directions but also in a longitudinal direction away from or towards the laser source (known as and referred to below as the 'Z'

direction). Techniques with the appropriate resolution to accurately track eyes undergoing surgery in the Z direction have not yet been fully developed.

US Patent 5,162,641 describes an eye tracking system, based on the principle of confocal microscopy, for measuring depth movement in eye tissue during laser surgery. This invention uses an illuminating light, a pinhole and a detector, located behind the optics of a laser system, to monitor the depth of a reflection along the optical axis. The system is arranged so that the maximum intensity of light reflected from the eye is directed onto the detector unit. The eye tracker focuses on an anterior reflective surface, such as the corneal tear layer, or a similar reference point with a known relationship to the target of the laser beam, and not necessarily on the target itself. When the tissue in the laser beam's focus moves, signals from the photodetector/pinhole arrangement decrease. These signal changes are then used to drive the optics of the laser system to compensate for the tissue movement, thereby moving the objective lens and repositioning the laser's focus. Focus monitoring may also be achieved by dithering the pinhole/photodetector unit to determine the direction in which signal increase occurs.

US Patent 5,336,215 (Intelligent Surgical Lasers) teaches an eye stabilizing mechanism for use with a computer controlled ophthalmic laser system, specifically for use in intrastromal PRK or phacoemulsification procedures. This laser delivery system employs suction to immobilise the eye. A contact lens with limbal suction eliminates the need for a non-contact eye tracking device. A moveable objective lens controls the position of the laser's focal point through the various tissues of the eye in the X and Y or Z directions. Nevertheless, devices such as the one described above are not ideal for use in intrastromal ablation procedures: they have the potential to raise

intra-ocular pressure, deform the shape of the eyeball and cause discomfort to the patient. The contact lens must also be made to conform to the individual patient's corneal topography. In addition, the reliance on suction to hold a device on the eye is one of the main reasons why current microkeratomes cause complications.

A technique that can be used to measure surface topography is optical coherence tomography (OCT). OCT usually involves splitting light from a low coherence light source (such as a superluminescent diode) and transmitting part of that light to the object of interest (for example, a cornea) and the rest to a reference surface (for example, a flat mirror). The light is then combined again at a detector. Only when the distance to the reference surface matches the distance to the object of interest do the light beams from the two paths interfere with each other to form intensity variations at the detector. The reference surface is usually scanned backwards and forwards so the intensity variations at the detector form a signal that is easily detected using electronic filters.

US Patent 5,465,147 describes a OCT based device for measuring surface topography. US Patent 5,644,642 teaches a gaze tracking device that employs OCT. This latter device uses measured height information of the features of the eye to improve the accuracy of tracking the eye in the X and Y directions. An optical fibre is used to transmit low coherence radiation onto a scanning reference mechanism, which causes a focal spot of radiation to scan the plane of the pupil transversely across the pupil/iris boundary. A raster pattern or a coarse scan pattern featuring a grid of points is employed and information is collected at each point on the grid. Radiation reflected from the eye interferes with that coming from the reference path, which has a known path length that may be varied intermittently. Output from the OCT device is then

generated when the path length of the reflected radiation is equal to the reference path length. An identifiable signal is produced when the scan crosses the pupil/iris border, enabling the determination of depth information. A computer examines the position at which a change in depth exceeds a predetermined amount. Spatial coordinates are then used in conjunction with geometric equations to determine the pupil border and pupil centre.

OCT thus provides an inexpensive, non-contact and non-invasive method of tracking depth points within the eye. However, OCT apparatus of the prior art scan a reference surface around the full range of possible signals from above and below the corneal surface to the interior of the eye, as well as scanning in X, Y directions, which is not highly effective as a tracking technique.

Scanning of the reference surface could, instead, be made to oscillate or dither around the equivalent position of a single surface, such as the anterior corneal surface or the iris. The electronic detection circuit could then lock on to the detector signal for the corneal surface and allow the surface to be tracked in real time and high resolution.

It is therefore an object of the present invention to provide an improved eye tracking system that can track the movement of an object in the axial or Z direction.

According to a first broad aspect of the present invention there is provided a method for detecting the position of a surface of an object including the steps of:

1) beam splitting a beam of light of low coherence;

2) reflecting a first component of said light onto a reference surface and a second component of said light onto said surface of said object;

3) forming an interference pattern of reflected

portions of said first and second components reflected from said reference surface and from said surface of said object respectively; and

4) identifying a reference surface position along the axis of the reference beam incident on said reference surface corresponding to a maximum in said interference pattern; whereby said position of said surface of said object may be deduced from said position of said reference surface corresponding to said maximum.

Preferably said method includes scanning said reference surface backwards and forwards along said axis of said reference beam.

Preferably said object is the cornea or the iris of an eye.

Preferably said method is used for intrastromal photorefractive keratectomy, Laser-in-situ-Keratomileusis procedures or laser optical breakdown in phacoemulsification, for directing the laser beam focal point to a position relative to said object.

Preferably said beam is of short coherence length light.

Preferably said method includes providing said beam by means of a superluminescent diode.

Preferably said reference surface is a high reflectance surface and more preferably a planar mirror.

Preferably said scanning is performed by means of a resonant, piezo or galvanometer scanner.

Preferably said imaging includes detecting said reflected light by means of a silicon diode detector.

According to a second broad aspect of the present invention

there is provided an apparatus for detecting the position of a surface within an object including:

a light source to provide a beam of light of low coherence;

a reference surface;

a beam splitter for splitting said beam into first and second components and directing said first component onto said reference surface and said second component onto said surface of said object;

beam scanning means for varying the position of said reference surface to vary the path length of said first component of said beam;

light detection means;

wherein an interference signal of reflected portions of said first and second components reflected from said reference surface and from said surface of said object respectively may be detected by said detection means and said beam scanning means may be used to vary the position of said reference surface until a maximum is identified in said interference signal, at which point said position of said surface of said object may be deduced from said position of said reference surface.

Preferably said beam scanning means is a dithering means.

Preferably said object is the cornea or the iris of an eye.

Preferably said apparatus is for intrastromal Photorefractive Keratectomy, Laser-in-situ-Keratomileusis procedures or laser optical breakdown in phacoemulsification, for directing the laser beam focal point to a position relative to said object.

Preferably said light beam is of short coherence length light.

Preferably said light source is a superluminescent diode.

Preferably said reference surface is a high reflectance surface and more preferably a planar mirror.

Preferably said scanning means is a resonant, piezo or galvanometer scanner.

Preferably said detector is a silicon diode detector.

According to a third broad aspect of the present invention there is provided an apparatus for tracking the focus spot of a laser beam at an object within an eye in ophthalmic laser surgery including:

a source of short coherence length light;

a beam splitter for splitting said beam into a first and second component along a reference path and an object path respectively;

a reference surface for reflecting the first component along said reference path and locatable, as an surface equivalent to said object within said eye, at a position equivalent to the position of said object, being a distance along said reference path equivalent to the distance of said object along said object path;

scanning means for varying the position of said reference surface about said equivalent position;

a detector for detecting the interference signal of light reflected from said reference surface and from said object; and

controller means for controlling the position of said spot of said laser;

wherein said equivalent position may be determined from a maximum in said interference signal detected with said detector and said controller means controls the position of said spot in response to a signal from said detector to maintain said spot at said object.

Preferably said laser includes optics controllable by said

controller means.

Preferably said apparatus includes a signal filter for filtering output of said detector before passing said signal to said controller means.

Preferably said scanning means is a first scanning means and said apparatus further includes a second scanning means for maintaining said first scanning means at said equivalent position.

Preferably said first scanning means is a dithering means.

Preferably said object is the surface of the cornea or the iris of an eye.

Preferably said laser surgery is intrastromal Photorefractive Keratectomy or Laser-in-situ-Keratomileusis procedures or laser optical breakdown in phacoemulsification.

Preferably said laser source is a short pulsed laser source, and more preferably an ultrashort Nd:YLF, Nd:YAG or Ti:Sapphire laser source.

Preferably said short coherence length light source is a superluminescent diode.

Preferably said reference path has a known path length, is varied periodically and can be varied to track the eye.

Preferably said reference surface is a flat mirror or high reflectance surface.

Preferably said scanning means are resonant, piezo or galvanometer scanners or any other suitable scanning mechanism or combination of scanning mechanisms.

Preferably said detector is a silicon diode detector or any other suitable detector.

Preferably said filter is a filter that filters noise and transmits just the interference signal.

Preferably said controller is a computer or electronic circuit.

According to a fourth broad aspect of the present invention there is provided a method for tracking the position of a surface of an object for aiming the focus spot of a laser beam in laser surgery, including:

1) splitting a beam of short coherence length light into reference and object beams;

2) deflecting said reference and object beams along a reference path and an object path respectively;

3) reflecting said reference beam from a reference surface and said object beam from said surface;

4) varying the position of said reference surface, as an surface equivalent to said surface, about a position equivalent to the position of said surface, being a distance along said reference path equivalent to the distance of said surface along said object path;

5) detector means for detecting patterns of interference of light reflected from said reference surface and from said surface and a maximum in said interference signal;

6) controlling the position of said spot of said laser according to said interference signal;

whereby said reference surface can be maintained at said equivalent position in response to said detected maximum and said spot can be controlled to be maintained at said surface according to said equivalent position.

Preferably said ophthalmic laser surgery includes IPRK,

cutting the flap in LASIK procedures or phacoemulsification procedures.

Preferably said ophthalmic laser surgery includes optical breakdown caused by a short laser pulse within the tissue of the eye.

In order that the invention may be more clearly ascertained, preferred embodiments will now be described, by way of example, with reference to the accompanying drawing in which:

Figure 1 is a schematic representation of a preferred embodiment of the present invention.

Figure 1 is a schematic view of an optical coherence tomography apparatus according to a preferred embodiment of the present invention, for tracking surfaces within a biological tissue, such as the cornea of the eye. The OCT apparatus directs a beam of short coherence length light 2, produced by light source 4, through beam splitter 6. Light source 4 is a superluminescent diode, producing a beam of visible or near infrared light. Beamsplitter 6 splits the beam into a reference beam 8 and a sample beam 10. The sample beam 10 is directed onto the surface 12 of the sample under examination (the cornea of an eye in the figure), while the reference beam 8 is directed onto a reference surface in the form of a flat mirror 14 which is scanned backwards and forwards in the direction of the reference beam 8 by means of dither scanning mechanism 16 and second scanning mechanism 18 (though in some embodiments scanner 16 may be omitted).

Light reflected from the mirror 14 interferes with reflected light from the sample surface 12 and produces a characteristic interference signal detectable at and by photo-detector 20, as reference mirror 14 is scanned as described above. However, the intensity variations of the

interference signal exist only when the total path length of the reference and sample beams 8 and 10 are equal. The position of mirror 14 is scanned so that the path length of reference beam 8 varies such that - when these total path lengths are equal - the output signal from detector 20 (and transmitted to filter 22) reaches a maximum intensity. Thus, the intensity of the electronic signal sent to filter 22 is dependent on the depth of the point of interest within the cornea. This signal may be analysed with respect to the position of scanner 18 to determine the signal peak that coincides with the position of the surface 12. Alternatively, the scanner 16 may be dithered around a previously determined position that corresponds to the surface 12, and the detected signal used to drive an offset to the position of the scanner 16 by second scanner 18 to keep the surface of mirror 14 in the middle of the dithered range. The dithered scanner 16 introduces a characteristic repetitive variation in the signal that can be filtered for efficient tracking. The position of the surface 12 can be read from the position of the scanner 18 in order to aim a surgical laser.

Thus, a novel OCT scanning apparatus may be used according to the present invention to enable the precise tracking of surfaces within the eye, in real time and high resolution. The apparatus scans mirror 14 only about a position corresponding to the peak of the electronic signal from filter 22. The scanning distance is equal to approximately ±1 to ±10 microns around the surface of the object (e.g. the cornea). This device is therefore capable of giving a very sensitive depth measurement in the Z direction (towards the eye) with a fast response time. During surgical procedures, a controller may interpret the signals and send instructions to a surgical laser system (not shown) to adjust the focal point of the laser according to movements of the patient's eye.

The OCT method and apparatus according to the present invention can provide information regarding the axial position of the cornea, enabling an ablative laser to be accurately focused on a spot within the cornea during operations such as intrastromal ablation or cutting the flap during LASIK. However, eye movements in the X and Y direction can still affect the placement of the laser beam. A second preferred embodiment of the present invention would, therefore, include gaze tracking apparatus capable of tracking translational eye movements. Any suitable means of horizontal and vertical eye tracking may be employed to detect alterations in the coordinates of the centre of the pupil, which indicate that horizontal or vertical eye movements have occurred. Adjustments in the laser's focal point can therefore be made in any direction, according to movements of the patient's eye.

Modification within the spirit and the scope of the invention may therefore be readily effected by a person skilled in the art. Optional infrared lights may be included to track eye gaze in the horizontal and vertical directions. Thus, it is to be understood that this invention is not limited to the particular embodiments described by way of example hereinabove.

DATED THIS 17TH DAY OF JUNE 1998
THE LIONS EYE INSTITUTE OF WESTERN AUSTRALIA INCORPORATED
By Its Patent Attorneys:
~~GRIFFITH HACK~~
Fellows Institute of Patent
Attorneys of Australia.

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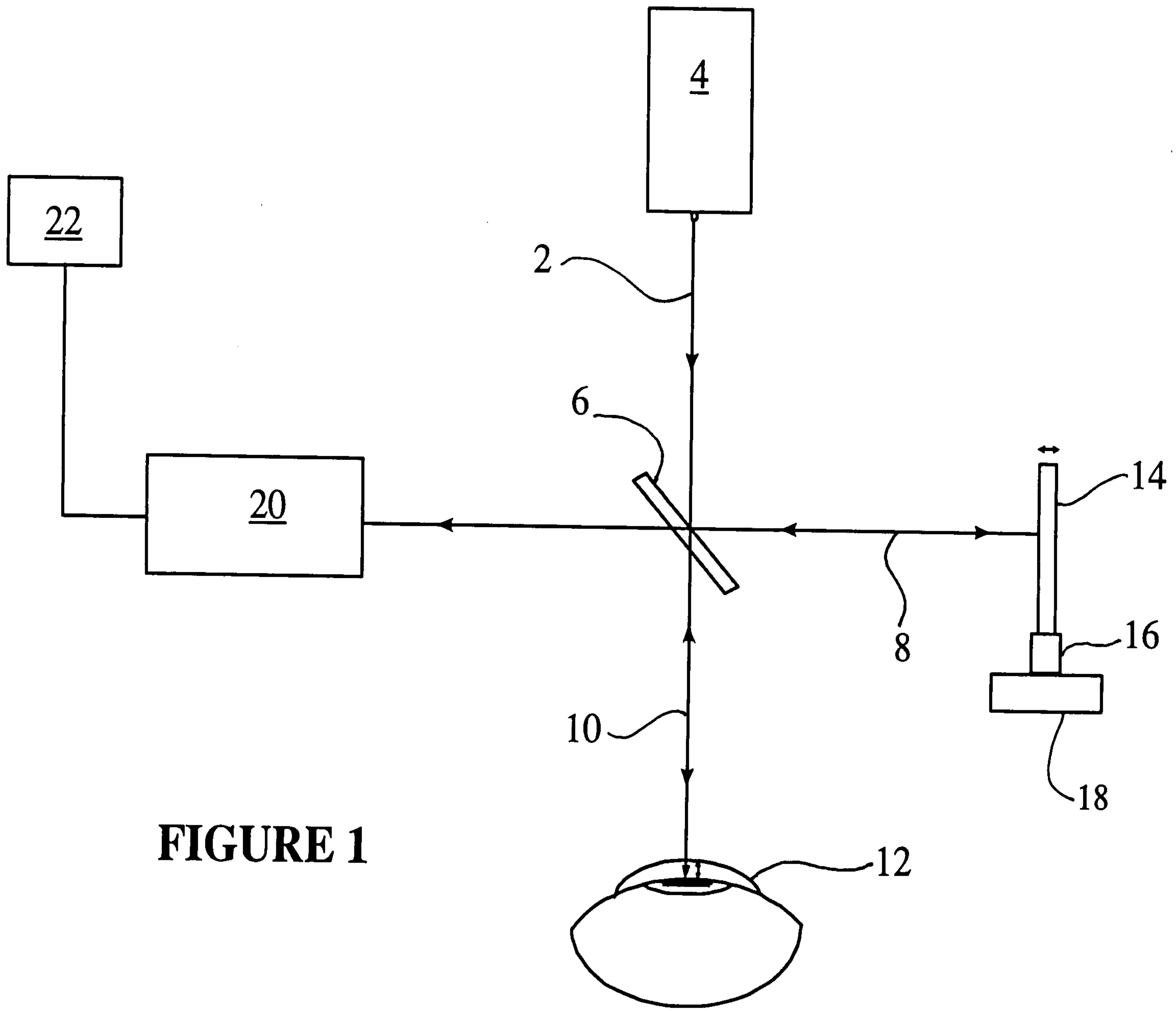

FIGURE 1